

b. assaying for the level of interaction of the TACI protein and the TACI-L protein;  
such that if the level obtained in step (b) differs from that obtained in the absence of test compound, a compound that affects the interaction of the TACI protein and the TACI-L protein is identified.

33. (new) The method of claim 31, wherein the fragment of the polypeptide of SEQ ID NO:2 is amino acids 1-166 of SEQ ID NO:2.
34. (new) The method of claim 31, wherein the fragment of the polypeptide of SEQ ID NO:4 is amino acids 73-285 of SEQ ID NO:4.

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### REMARKS

Claims 15-28 are pending and have been rejected. Claims 15, 21 and 26 have been amended. New claims 29-34 have been added. Support for these amendments and new claims may be found throughout the specification and in the claims as originally filed. No new matter has been added.

#### Rejection under 35 USC § 112, first paragraph

The Examiner rejected claims 15-28 under 35 USC § 112, first paragraph, alleging that the disclosure was not enabling. Specifically, the Examiner asserted that essential material, the definitions of TACI and TACI-L, was incorporated by reference. Applicants have amended the specification to specifically state the definitions of TACI and TACI-L. Support for the amendments may be found in pages 5-7 of WO 98/39361; pages 9- 10, bridging paragraph, of WO 98/18921; page 2-4 of WO 98/27114; and page 3, lines 18-19, of EP 0869180 A1. The amendatory material consists of the same material incorporated by reference in the referencing application. No new matter has been added.

The Examiner further rejects claims 15, 23 and 24 under 35 USC § 112, first paragraph, alleging that the specification does not provide enablement for assaying for the levels of interaction of the TACI protein and the TACI-L protein, wherein said assaying comprises assessing activation of TACI in a cell, wherein said assaying is measured by calcium influx. Applicants respectfully traverse.

The method of measuring calcium influx as a standard of assessing activation of TACI in a cell is known in the art. Applicants direct the Examiner to pages 64-65 of WO 98/39361, which describe such a method. As the Examiner admits, the instant

specification enables the skilled artisan to assay for the level of binding between TACI and TACI-L. Thus, the skilled artisan would have sufficient guidance from the instant specification and methods known in the art to make and/or use the claimed invention.

The Examiner further rejected claims 15-28 under 35 USC §112, first paragraph, because the specification allegedly fails to adequately define TACI, TACI-L, their allelic variants, homologs, and analogs. The Examiner also stated that the specification fails to identify those amino acid residues in the amino acid sequence of TACI or TACI-L that are essential for their biological activity.

As discussed above, applicants have amended the specification to specifically recite the definitions of TACI and TACI-L. Applicants respectfully direct the Examiner to page 6, lines 4-13, and page 7, lines 10-19, which define homologous analogs of TACI and TACI-L, and to the final paragraph of page 5 and the first paragraph of page 7, which give examples of amino acid residues of TACI or TACI-L which are essential for the biological activity of TACI or TACI-L. In order to further clarify what is claimed in this application, applicants have amended claim 15 to include particular embodiments of TACI and TACI-L. Applicants may wish to pursue claims reciting other embodiments in a continuation application. From the specification and the above amendment, the skilled artisan would understand how to make and/or use the instant claimed invention.

The Examiner still further rejected claims 15-28 under 35 USC §112, first paragraph, stating that the specification allegedly did not convey that the inventors had possession of the claimed invention at the time the application was filed.

As discussed above, applicants have amended the specification to specifically recite the definitions of TACI and TACI-L. Applicants respectfully direct the Examiner to page 6, lines 4-13, and page 7, lines 10-19, which define homologous analogs of TACI and TACI-L. Applicants further direct the Examiner to the final paragraph of page 5 and the first paragraph of page 7, which give examples of amino acid residues of TACI or TACI-L which are essential for the biological activity of TACI or TACI-L. From the specification and the above amendment, the skilled artisan would understand that the inventors had possession of the claimed invention at the time the application was filed.

In light of the above amendments and discussion, the rejections under 35 USC §112, first paragraph, are obviated and should be withdrawn.

**Rejection under 35 USC §112, second paragraph:**

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The Examiner rejected claims 15-28 as indefinite because the claims recite the terms "TACI" and "TACI-L", which the Examiner states are not clearly defined by the specification. As discussed above, applicants have amended the specification to more clearly define the terms "TACI" and "TACI-L."

The Examiner stated that there is a lack of antecedent basis for the limitation of claim 21. Applicants have amended the claim to recite "wherein the composition is formed by adding the test compound to a composition comprising the TACI protein and the TACI-L protein" as suggested by the Examiner.

The Examiner pointed out that claim 26 depends from itself. Applicants have corrected claim 26 to recite its dependence from claim 25.

No new matter has been added. In light of the above amendments and discussion, applicants request that this rejection be withdrawn.

**Rejection under 35 USC § 103:**

The Examiner rejected claims 15, 19, 20, 23 and 25 under 35 USC § 103(a) as being allegedly unpatentable over Chaudhary in view of Bringman. The Examiner asserts that Chaudhary discloses a method of forming a composition of BJAB cells with TACI-L. The Examiner further asserts that BJAB cells are TACI proteins as recited in the as-filed specification. The Examiner states that Bringman teaches how to make a neutralizing antibody and in light of that teaching and Chaudhary's disclosure, the claimed invention would be obvious.

Applicants traverse this rejection and assert that "TACI" does not include BJAB cells. The specification has been amended to include materials previously incorporated by reference, which explicitly define TACI as a polypeptide having amino acid sequences set forth in SEQ ID NO:2 or allelic variants thereof. Thus, TACI could not be interpreted to include BJAB cells. Chaudhary, therefore, does not teach forming a composition of TACI and TACI-L and Bringman fails to remedy this deficiency.


In light of this understanding and deficiency, this rejection is obviated and should be withdrawn.

Applicants respectfully request entry and consideration of the above amendments. If the Examiner believes that any issues outstanding could be addressed by way of a

telephone conference, the Examiner is invited to telephone to undersigned.

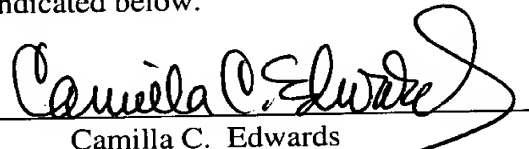
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**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date indicated below.

Date: April 13, 2007      Signed:   
Camilla C. Edwards

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## APPENDIX I

### Marked up version of each amended paragraph:

**On page 5, the paragraph beginning at line 28, amended to read:**

The terms “TACI” and “TACI protein” are used interchangeably to define the TNF receptor disclosed by WO 98/39361 and refer, among others, generally to a polypeptide having the amino acid sequence set forth in SEQ ID NO:2 or a homologous analog thereof. TACI comprises an extracellular domain, a transmembrane domain, and cytoplasmic domain.

**On page 5, the paragraph beginning at line 31, amended to read:**

“Fragments” of TACI encompass truncated amino acid sequences of the TACI protein that retain the biological ability to bind to TACI-L. An example of such a fragment is the extracellular domain. One embodiment of the extracellular domain has the amino acid sequence of amino acids 1-166 of SEQ ID NO:2. In another embodiment of the extracellular domain, the domain has the amino acid sequence of amino acids 1-166 of SEQ ID NO:2 with one or more conservative substitutions. Such fragments are identified in WO 98/39361, which is incorporated in this application in its entirety.

**On page 6, the paragraph beginning at line 27, amended to read:**

The terms “TACI-L” and “TACI ligand” are used interchangeably to define the member of the TNF ligand family disclosed by WO 98/18921 and refer, among others, generally to a polypeptide having the amino acid sequence set forth in SEQ ID NO:4 or a homologous analog thereof. TACI-L is also disclosed as “TL5” in EP 0869180A1 and as “63954” in WO 98/27114. The full-length TACI-L comprises an extracellular domain, a transmembrane domain, and a cytoplasmic domain. Although the exact location of the extracellular, transmembrane, and cytoplasmic domains may differ slightly due to different analytical criteria for identifying the functional domains, the range of amino acids 1 to 46 generally represents the intracellular domain; amino acids 47 to 72 represent the transmembrane domain, and amino acids 73-285, the extracellular domain.

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**APPENDIX II**  
**Marked up version of each amended claim:**

15. (amended) A method of screening a test compound to identify its ability to affect the interaction of TACI with TACI-L, the method comprising the steps of:

a. forming a composition comprising (i) a TACI protein, wherein said TACI protein comprises a polypeptide selected from the group consisting of:

- (a) the polypeptide of SEQ ID NO:2;
- (b) fragments of the polypeptide of SEQ ID NO:2; or
- (c) a polypeptide encoded by a nucleic acid sequence that is at least 75% identical to SEQ ID NO:1; wherein said polypeptides and fragments of (i) (a), (b) and (c) bind TACI-L;

(ii) a TACI-L protein, wherein said TACI-L protein comprises a polypeptide selected from the group consisting of:

- (a) the polypeptide of SEQ ID NO:4;
- (b) fragments of the polypeptide of SEQ ID NO:4; or
- (c) a polypeptide encoded by a nucleic acid sequence that is at least 75% identical to SEQ ID NO:3; wherein said polypeptides and fragments of (ii) (a), (b) and (c) bind TACI; and

(iii) the test compound; and

b. assaying for the level of interaction of the TACI protein and the TACI-L protein;

such that if the level obtained in step (b) differs from that obtained in the absence of test compound, a compound that affects the interaction of the TACI protein and the TACI-L protein is identified.

21. (amended) The method of claim 15 wherein the [test compound is added to the composition after the addition of the TACI-L protein] composition is formed by adding the test compound to a composition comprising the TACI protein and the TACI-L protein.

26. (amended) The method of claim 25[26] wherein the soluble extracellular TACI-L comprises a leucine zipper domain.

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